K 983065

DEC 1 1998

510(k) SUMMARY

Date: November 23, 1998

Submitter: Donna A. Crawford
Manager, Corporate Regulatory Affairs
Mentor Corporation
5425 Hollister Avenue
Santa Barbara, CA 93111
Phone: 805-681-6000
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Trade or Proprietary Name: Solid probe (accessory to Mentor® Ultrasound-Assisted Tissue Removal System)

Common or usual name: Solid probe

Description and Intended Use of Device:

The Mentor Ultrasound-Assisted Tissue Removal System (TRS) consists of the following components: ultrasonic generator, infiltrator, aspirator, ultrasonic handpiece, foot pedal(s), hollow cannulae and cannulae sheaths, system cart, irrigation tubing set, infiltration tubing set, and aspiration tubing set. The Mentor (TRS) is indicated for the liquefication and aspiration of soft tissues in General Surgery, Plastic and Reconstructive Surgery and Gynecological Surgery applications.

The purpose of this 510(k) notification is to add a solid probe as an accessory to the Mentor TRS. The solid probe is composed of Titanium 6Al-4V and will be available in three diameters (3 mm, 4 mm, and 5 mm) in lengths of 4 cm to 45 cm. The probe is connected to the handpiece with a threaded screw-fit. The tip has a spherical shape.

Substantial Equivalence:

The solid probe is substantially equivalent to the hollow cannula currently used with the Mentor TRS which was cleared under 510(k) K970471, as follows:

	Mentor TRS Hollow Cannula 510(k) K970471	Mentor TRS Solid Probe
Operating Frequency (typical)	27 kHz	27 kHz
Amplitude (maximum)	130μ peak-to-peak	130μ peak-to-peak
Attachment Method	Threaded screw fit	Threaded screw fit
Material	Titanium 6Al-4V	Titanium 6Al-4V
Outside diameter (O.D.)	3 mm, 4 mm, 5 mm	3 mm, 4 mm, 5 mm
Length	4 to 45 cm	4 to 45 cm
Inner diameter (I.D.)	1.98 mm, 2.26 mm, 2.54 mm	Not Applicable
Tip Shape	Bullet and spherical	Spherical
Sterilization Method	Steam autoclave	Steam autoclave

The Mentor solid probe is also substantially equivalent to other solid probes currently on the market, such as the solid probe used with the SMEI Sculpture ultrasonic aspiration system which received clearance under 510(k) K971609. Both are made of solid titanium and are used in the same manner for the same intended use. The Mentor solid probe has a spherical tip, while the SMEI Sculpture probe does not.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 1998

Ms. Donna A. Crawford
Manager, Corporate Regulatory Affairs
Mentor Corporation
5425 Hollister Avenue
Santa Barbara, California 93111

Re: K983065
Trade Name: Mentor Ultrasound-Assisted Tissue Removal System
Regulatory Class: II
Product Code: LFL
Dated: September 1, 1998
Received: September 2, 1998

Dear Ms. Crawford:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation

510(k) Number (if known): K983065

Device Name: Mentor® Solid Probe (accessory to Mentor Ultrasound-Assisted Tissue Removal System)

Indications For Use:

The Mentor Ultrasound-Assisted Tissue Removal System is indicated for the liquefication and aspiration of soft tissues in General Surgery, Plastic and Reconstructive Surgery and Gynecological Surgery applications.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983065

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)